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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/774,082

02/05/2004

Dennis Brian Rylatt

LIFT-029/01US

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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

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07/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/774,082	Applicant(s) RYLATT ET AL.	
	Examiner Lisa V. Cook	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-58 is/are pending in the application.
- 4a) Of the above claim(s) 39-47, 50, 52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-38, 48, 49, 51, 53 and 55-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 22-58 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' response to the Restriction Requirement mailed 10 October 2006 is acknowledged (reply filed 12/7/06). Currently, claims 22-58 are pending.
2. Applicant's election with traverse of Group I (claims 22-38, 48, 49, 51, 53 and 55-58) in the reply filed on 12/7/06 is acknowledged. The traversal is on the ground(s) that the instant invention is directed to a membrane-based method and apparatus. The instant invention must be considered as a whole and would provide a contribution over the prior art. This argument has been carefully considered but not found persuasive because membrane-based methods and apparatus are taught by the prior art.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. Applicant contends that the special technical feature linking claims 22-58 is a membrane-based method and apparatus. However, the reference of Horvath et al. (Electrophoresis, 1996, Vol.17, pages 224-226) discloses that the Gradiflow system in conjunction with affinity membranes extended the capabilities of the already multifunctional Gradiflow system. See abstract and figure 1. The instant disclosure employs the Gardiflow system. See page 1 lines 20-24. Therefore the technical feature recited in claims 22-58 is not a contribution over the prior art. Accordingly the claims are not so linked as to form a single general concept under PCT Rule 13.1.

The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

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3. Currently, claims 22-58 are subject to Restriction and Election Requirement. Claims 39-47, 50, 52, and 54 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 22-38, 48, 49, 51, 53, and 55-58 are currently under examination.

***Priority***

4. If applicant desires priority under 35 U.S.C. 120 to application number 09/701,818 filed December 1, 2000 - now abandoned; based upon previously filed applications, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application.

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If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

5. The instant application should be updated to include the correct status of application number 09/701,818 on page 1. Please include 09/701,818 filed December 1, 2000 - *now abandoned* to the specification.

### ***Information Disclosure Statement***

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered. Please see references cited through out the disclosure and on page 13.

### ***Specification***

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

A. The disclosure is objected to because of the following informalities:

On page 5 lines 17-19 and page 10 lines 28-30, the term *Table I* is identified however Table I does not exist in the instant specification. It is suggested that the term "Table I" be replaced with Table 1 in order to eliminate ambiguity. Please correct.

B. The use of the trademark TWEEN has been noted in this application. See page 8 for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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8. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 24, 25, 26, 28, 29, 32, 33, 34, 35, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 24, 25, 26, 28, 29, 32, 33, 34, 35, 36, and 37 recite the limitations "between about", "about", and "at least about". These are relative terms rendering the claims indefinite because the intended range is not clear. When a word of degree is used as a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. V. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art to reasonably establish what may be construed as being within the metes and bounds of the word of degree.

Therefore, one of ordinary skill in the art would not be apprised as to the claimed invention's scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641.

It is suggested that the ambiguous language be omitted in order to clearly set forth the intended ranges. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**I.** Claims 55-58 are rejected under 35 U.S.C. 102(a) as being anticipated by Lim et al.

(Abstract presented on 31/05/1998 at the 1998 International symposium on preparative Chromatography, Ion Exchange and Adsorption/Desorption Process and Related Techniques, Washington DC, ETATS-UNIS).

Lim et al. disclose four monoclonal antibodies purified from ascetic fluid via electrophoresis procedures. See abstract. It is noted that the procedures of purification do not further limit the purified antibody compositions recited in claims 55-58.

**II.** Claims 22, 24, 25, 26, 28, 29, 48, 51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Horvath et al. (Electrophoresis, Vol.15, 1994, pages 968-971).

Horvath et al. disclose a multifunctional apparatus for separating macromolecules into one of two streams based on charge and/or size differences. The apparatus employed is the Gardiflow system that is also taught in the instant specification on page 1. The system or apparatus contains a sample network with two streams (upstream and downstream).

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This reads on Applicants first and second fluid stream. The system includes multiple membranes; two outer membranes and a central separating membrane (first selective membrane). See abstract and page 968 – 2<sup>nd</sup> column. The membranes enable a wide range of molecular cutoffs. See page 969 1<sup>st</sup> column – 1<sup>st</sup> paragraph. The system can be utilized to concentrate/separate proteins of interest from contaminants via charge (figure 1a), and size (figure 1b), and concentration (figure 1c), and electrodialysis (figure 1d). The principle of size and charge based mode is described on page 970. In one embodiment, contaminants with a pI or isoelectric point lower than that of the target (Applicants at least one antibody) are removed. See page 969 1<sup>st</sup> column last sentence.

The Gradiflow apparatus was used to fraction albumin-depleted serum (all proteins over approximately 70kDa were removed) and phycoerythrin purification (the separating membrane permitted all proteins smaller than 240 kDa to pass down stream. Reading on claims 24-25. The resulting yield of phycoerythrin (target) was over 85% (reading on claims 28 and 29). The separation process was conducted at a pH of 8.3 (reading on claim 26). See page 970 - 2<sup>nd</sup> column.

Although Horvath et al. are silent with respect to the target protein comprising an antibody, this is deemed an inherent limitation because protein comprise antibody compositions and Horvath et al. employ the same Gadiflow separation system as taught by the instant invention (for example see specification page 1). Accordingly, the Gadiflow system would necessarily be able to separate at least one antibody from contaminants.

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In considering the anticipatory effect of a reference, not only its specific teachings but also the inferences which one skilled in the art would reasonably expect to draw therefrom should be taken in to account. *In re Preda* (CCPA 1968) 401 F2d 825, 159 USPQ 342. Same, that which necessarily flows from what is described. *Ex parte Bylund* (POBA 1981) 217 USPQ 492.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

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**III.** Claims 27, 30-38 and 49 are rejected under 35 U.S.C. 103(b) as being unpatentable over Horvath et al. (Electrophoresis, Vol.15, 1994, pages 968-971) in view of Corthals et al. (Journal of Chromatography A, Vol. 773, 1997, pages 299-309).

Please see Horvath et al. (Electrophoresis, Vol.15, 1994, pages 968-971) as set forth above.

Horvath et al. (Electrophoresis, Vol.15, 1994, pages 968-971) differ from the instant invention in not specifically teaching the inclusion of a series of cycles involving stopping and reversing the procedure (forward phase and reverse phase) with additional membranes (second selective membrane).

However, Corthals et al. teach protein purification procedures utilizing the Gradiflow apparatus. The process combines the use of molecular mass exclusion membranes with electrophoresis. The researchers utilize a reflux electrophoresis technique that consists of a series of cycles incorporating a forward phase (collection of a target protein that passes through a separation membrane before trailing proteins in the same solution). The forward phase is repeated following clearance of the membrane in the reverse phase by reversing the current. Various membranes are chosen for optimal operating procedures and protein transfer is monitored at different pH values. See abstract and figure 1.

Corthals et al. separated the wallaby whey protein with two different membranes while the buffer conditions were kept constant. In the separation of recombinant PsA different membranes and different buffer conditions (pH) were utilized. See page 301 section 2.4, page 302 section 2.5, and Table 1.

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Because protein migration can be unpredictable, Corthals et al. suggest the performance of a series simple experiments to monitor the proteins a different pH values with a set of membranes having varying pore size (different molecule weight cutoffs). See page 308 2<sup>nd</sup> column through page 309 -1<sup>st</sup> column 1<sup>st</sup> paragraph. The paper demonstrates that feasibility of the reflux system in protein purification. See page 309.

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to utilize the reverse phase cycling procedure with various membranes as taught by Corthals et al. in the protein purification procedure of method of Horvath et al. because Corthals et al. taught that this was simple and useful in analyzing unpredictable protein migration. See page 308 2<sup>nd</sup> column through page 309 -1<sup>st</sup> column 1<sup>st</sup> paragraph.

One having ordinary skill in the art would have been motivated to use the reflux procedures because Corthals et al. demonstrated the feasibility of the reflux system in protein purification. See page 309.

IV. Claim 23 is rejected under 35 U.S.C. 103(b) as being unpatentable over Horvath et al. (Electrophoresis, Vol.15, 1994, pages 968-971) in view of Lim et al. (Abstract presented on 31/05/1998 at the 1998 International symposium on preparative Chromatography, Ion Exchange and Adsorption/Desorption Process and Related Techniques, Washington DC, ETATS-UNIS).

Please see Horvath et al. (Electrophoresis, Vol.15, 1994, pages 968-971) as set forth above.

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Horvath et al. (Electrophoresis, Vol.15, 1994, pages 968-971) differ from the instant invention in not specifically monoclonal antibody purification from ascetic fluid.

However, Lim et al. teach antibody purification from ascetic fluid involving electrophoresis. The antibody recovery was over 80% and the method is taught to be a cost effective alternative to protein A chromatography. See abstract.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to purify monoclonal antibodies from ascetic fluid as taught by Lim et al. in the electrophoresis method of Horvath et al. because Lim et al. taught that the antibody recovery was over 80% and the method could be a cost effective alternative to protein A chromatography. See abstract.

7. For reasons aforementioned, no claims are allowed.
8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

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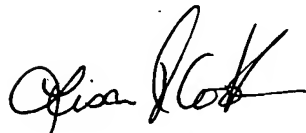
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

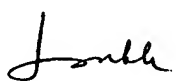
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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7/7/07



LONG V. LE 07/09/07  
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